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Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
(302) 774-6443

2-1595

ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard[2]. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.[3] Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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[2]In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not.exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent[4], the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).

o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.

othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.[5];

othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

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[4]The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

[5] *See, e.g,* 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

> Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). *See also*, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

> ...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

> "a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See,* 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy",43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	}[6]	}[7]
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	Y[8]
SKIN SENSITIZATION (ANIMALS)	N	Y[9]
EYE IRRITATION	N	Y[10]
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y[11]
REPRODUCTION STUDY	N	Y[12]
DEVELOPMENTAL TOX	Y[13]	Y[14]

[6] 43 Fed Reg at 11114, comment 14:
"This policy statements directs the reporitng of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

[7] Guide at pp.22, 29-31.

[8] Guide at pp-34-36.

[9] Guide at pp-34-36.

[10] Guide at pp-34-36.

[11] Guide at pp-22; 36-37.

[12] Guide at pp-22

[13] 43 Fed Reg at 11112
"Birth Defects" listed.

[14] Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y}[20]	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

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[15] Guide at pp-23; 33-34.

[16] 43 Fed Reg at 11112
"Cancer" listed

[17] Guide at pp-21.

[18] 43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19] Guide at pp-23.

[20] 43 Fed Reg at 11112; 11115 at Comment 16.

CAS # 13252-14-7
Chem: 3,6-Dioxa-2,5-di(trifluoromethyl)ondafluoronanoic acid fluoride
Title: Acute skin absorption toxicity test; eye irritation test
Date: 6/1/65
Summary of Effects: ALC 100 ppm (4 hr exposure)

MR-604-1

Copies to: W. J. Brehm (4)
G. F. Curtin (1)
E. H. Zytkus (1)

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine

HASKELL LABORATORY REPORT NO. 73-65 MR NO. 604

Material Tested: HFPO Trimer
3,6-dioxa-2,5-di(trifluoromethyl)undecafluorononanoic acid fluoride

Haskell No.: 3594

Material Submitted by: A. M. Grimaldi, Plastics Department, Research & Development Division

Other Codes: None

ACUTE SKIN ABSORPTION TOXICITY TEST

Procedure: The calculated doses of the material as a 50% emulsion in dimethyl phthalate were gently rubbed into the closely clipped dorsal skin of male albino rabbits. The rabbits were restrained in wooden stocks during and for about an hour after treatment. Survivors were sacrificed two weeks after exposures.

Results:

Dose (mg/kg)	Mortality*	Clinical Signs of Toxicity		Significant Gross Pathologic Changes	Histology
		Systemic	Local		
2250	(d) < 24 hours	None observed	Moderate irritation		Advanced post-mortem changes hindered interpretation of cellular changes. Epidermal necrosis and sloughing seen in the rabbits that died. No other effects attributable to the compoun were seen in any of th rabbits
1500	(d) 26 hours	Quiet, moved only when prodded; when walking bent front paws under, did not eat or drink	Mild irritation	Mild cyanosis	
1000	(d) 48 hours	Unusually quiet; no food or water consumed first night	Strong becoming mild	Dehydration	
670	(d) < 72 hours	Unusually quiet for 24 hours; some loss of appetite	Mild	Mild cyanosis	
450	(s) 14 days	Sporadic weight loss	Mild for 24 hours		

06/22/1992

Dose (mg/kg)	Mortality*	Clinical Signs of Toxicity		Significant Gross Pathologic Changes	Histology	ALD
		Systemic	Local			
300	(s) 14 days	Slight weight loss	Strong to moderate becoming normal in 3 days	-	See Page 1	670 mg/kg
200	(s) 14 days	None	Moderate to mild becoming normal in 9 days	-		

ALD = 670 mg/kg

* (d) = died; (s) = sacrificed

EYE IRRITATION TEST

Procedure: One-tenth ml of the test material was instilled into the conjunctival sac of one eye of each of two rabbits. Twenty seconds after contact, one eye was washed with water for 1 minute; the other eye was not washed. Daily examinations with a hand slit lamp, before and after fluorescein staining, were made for four days after treatment. An interim examination was made at seven days, with a final examination at five weeks.

Results:

Treatment	Ocular Effects		
	Cornea	Iris	Conjunctivae
Eye washed	Mild opacity for 2 days, moderate opacity at 3 through 7 days. Dense scars and vascularization at 5 weeks.	Mild iritis through 7 days	Severe conjunctivitis through 2 days, subsiding to mild at 7 days
Eye not washed	Mild opacity through 3 days, moderate at 4 through 7 days, vascularization at 7 days. Dense scars and vascularization at 5 weeks.	Mild iritis through 7 days	Severe conjunctivitis through 7 days

ACUTE INHALATION TOXICITY

Procedure: The test material was metered at a known rate by a mechanical syringe drive into a T-tube heated to 100-110°C. A dry air stream carried the resulting vapor into an 8-liter bell jar containing four ChR-CD male rats of initial body weight 241-296 grams per exposure.

Results:

Nominal Concentration (ppm)	Air Flow (liter/min.)	Period of Exposure (hrs.:min.)	Liver Wt./Body Wt. x 100	Mortality Ratio	Fate
250	2.14	4:00	N.D.	4/4	All found dead 1 day after exposure
150	3.54	4:00	N.D.	4/4	Three found dead 1 day following exposure, remaining animal died 5 days after exposure
100	2.73	4:00	N.D.	4/4	Three found dead 1 day following exposure, remaining animal died 5 days after exposure
50	2.75	4:00	9.38	0/4	All killed 14 days after exposure

Observations During Life: The Approximate Lethal Concentration of the test material was 100 ppm for a single exposure of four hours. At lethal concentrations, the clinical signs observed during the exposure were lacrimation, salivation, discomfort, ruffled and yellow fur, clear fluid around nose, rapid deep respiration followed by labored respiration with gasping, cyanosis, and inactivity. After exposure to lethal concentrations, the rats showed weakness, inactivity, rapid and labored respiration with rales and occasional gasping, dried blood around the nose, and ruffled fur. Animals exposed to sublethal concentrations exhibited inactivity, rapid respiration, and red ears while being exposed. Following exposure, they showed no clinical signs of toxicity.

Rats exposed to the lower lethal concentrations (150 ppm and 100 ppm) that lived 1-5 days after exposure showed a large initial and continuous weight loss. Animals receiving sublethal concentrations showed no weight losses during the 14-day observation period.

Pathology: Inhalation of HFPO trimer caused pulmonary edema and congestion at all levels tested. At lethal levels, it also caused emphysema and pulmonary hemorrhage. It also caused an increase in liver size. Animals exposed at 50 ppm had livers almost twice the normal weight when killed 14 days after exposure. Microscopic examination of the tissues revealed that the liver cells were enlarged and the reticuloendothelial cells were greatly increased in number. No microscopic changes were observed in the other organs examined (brain, kidney, spleen, thymus, testis, bone marrow, duodenum, pancreas and stomach).

Summary: HFPO trimer was highly toxic and irritating to rats by inhalation. The liquid was moderately toxic to rabbits by skin absorption and was strongly irritating to all animal tissues with which it came in contact.

The Approximate Lethal Concentration (ALC) by inhalation, was 100 ppm for a four-hour exposure. The Approximate Lethal Dose (ALD) by skin absorption, was 670 mg/kg. Two drops of the liquid caused permanent dense scarring of the cornea when dropped into a rabbit's eyes. The scarring was unalleviated in one eye that was washed after dosing.

The irritant effects caused by both the HFPO trimer vapor and liquid were persistent. Rats exposed to a nominal 50 ppm for four hours still showed pulmonary edema and congestion when sacrificed 14 days after exposure. The local erythema produced by application of the liquid to rabbit skin persisted for nine days.

Inhalation of the compound for four hours at a nominal 50 ppm caused a doubling of rat liver weight by 14 days post-exposure. No corresponding liver effect was found in rabbits after skin application of HFPO trimer.

HFPO trimer not only has the toxicological properties expected of a reactive acid fluoride, but it also has a characteristic, detrimental effect on the liver. Thus, in addition to the basic industrial hygiene practices pertinent to the handling of acid fluorides, it is also recommended HFPO trimer be handled only by competent, previously instructed personnel in well ventilated areas. It is further recommended that splash-proof goggles be worn when working with this compound. Adequate clothing to prevent skin contact from spills is also recommended. Inhalation of vapors should be kept to a minimum. Clothing contaminated by this material should be immediately removed and washed in non-commercial facilities before reuse. Contaminated skin areas should be immediately flushed with large amounts of cold water.

Report by: R. J. NEHER

C. H. Tapscott

Richard S. Ward

Approved by: John A. Zapp Jr.

RSW/RJN/CHT:mfs
Date: June 1, 1965

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Mark H. Christman
Counsel
E. I. Du Pont De Nemours and Company
Legal D-7010-1
1007 Market Street
Wilmington, Delaware 19898

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12107A

Triage of 8(e) Submissions

Date sent to triage: APR 20 1995 NON-CAP (CAP)

Submission number: 12107A TSCA Inventory: Y N (D)

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

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entire document: (0) 1 2 **pages** 1, 1st TABS **pages** 1, TABS

Notes:

Contractor reviewer : PR **Date:** 4/3/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092-12107 SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: E.I. Dupont de Nemours and Company

SUB. DATE: 10/15/92 OTS DATE: 10/27/92 CSRAD DATE: 02/15/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0629) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME: Fluorononanoic acid Fluoride, 3,6-dioxa-2,5-di(trifluoromethyl)onda-

CAS#: 13252-14-7

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RBT	LOW		
CAS SR	NO	NO (CONTINUE)	RAT	MED		
	(DETERMINE)	REFER		(HIGH)		

COMMENTS

8(E)-12107A

M/H/H

ACUTE DERMAL TOXICITY IN MALE ALBINO RABBITS IS OF MEDIUM CONCERN BASED ON AN LD50 BETWEEN 450 MG/KG AND 670 MG/KG. DOSAGES (1-HOUR) AND MORTALITY DATA ARE AS FOLLOWS: 200 MG/KG (0/1); 300 MG/KG (0/1); 450 MG/KG (0/1); 670 MG/KG (1/1); 1000 MG/KG (1/1); 1500 MG/KG (1/1); AND 2250 MG/KG (1/1). TOXIC SIGNS INCLUDED MILD TO STRONG SKIN IRRITATION AND REDUCED ACTIVITY. GROSS PATHOLOGY REVEALED MILD CYANOSIS.

ACUTE EYE IRRITATION IN RABBITS IS OF HIGH CONCERN BASED ON MILD OPACITY, MILD IRITIS, SEVERE CONJUNCTIVITIS DURING THE FIRST WEEK AND PERMANENT DENSE CORNEAL SCARS AND VASCULARIZATION AT 5 WEEKS (2/2 UNWASHED, 2/2 WASHED) FROM EXPOSURE TO 0.1 ML.

ACUTE INHALATION TOXICITY IN MALE CD RATS IS OF HIGH CONCERN BASED ON AN LC50 BETWEEN 50 PPM AND 100 PPM. DOSAGES (4-HOURS) AND MORTALITY DATA ARE AS FOLLOWS: 50 PPM (0/4), 100 PPM (4/4), 150 PPM (4/4), AND 250 PPM (4/4). AT 100 PPM AND ABOVE, TOXIC SIGNS INCLUDED LACRIMATION, DEEP AND LABORED RESPIRATION, SALIVATION, AND GASPING. GROSS PATHOLOGY REVEALED PULMONARY EDEMA, CONGESTION, EMPHYSEMA, PULMONARY HEMORRHAGE, AND INCREASE IN LIVER SIZE. BY MICROSCOPIC EXAMINATION, LIVER CELLS WERE ENLARGED AND RETICULOENDOTHELIAL CELLS WERE GREATLY INCREASED IN NUMBER.